

REMARKS

Claims 1-11, 13-16 and 18 are pending and are rejected. Claims 4 and 18 are canceled.

Applicant respectfully requests reconsideration of the Examiner's rejections for the following reasons, retaining the Examiner's paragraph designations for convenience.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 2-3, 7, 11, and 15-16 are rejected under 35 U.S.C. § 112 ¶ 2 as indefinite.

6. Applicant respectfully disagrees that the Examiner's cited phrases are indefinite. Applicant's Declaration, submitted as part of this Amendment, provides that one skilled in the art knows how to calculate a maintenance dose from a daily dose to a monthly dose based on individualized bioavailability data (for example, page 6, line 16 to page 7, line 9 indicating how the maintenance dose is determined ("The maintenance dose of hGH is determined by evaluating the individual's response to serially increased doses of hGH, usually over one to two months. The dose is adjusted at about two to four week intervals, and in a range equal to that of the initial dose. For example, a male receiving an initial dose of 2 µg/kg/day would receive a serially increased dose of 4 µg/kg/day for two to four weeks, then a dose of 6 µg/kg/day for two to four weeks, then a dose of 8 µg/kg/day for two to four weeks, etc., until the maintenance dose is achieved. A female receiving an initial dose of 4 µg/kg/day would receive a serially increased dose of 8 µg/kg/day for two to four weeks, then a dose of 12 µg/kg/day for

two to four weeks, etc., until the maintenance dose is achieved”), how the monthly dose is administered (“Once the maintenance dose is achieved, a monthly dose of hGH is administered. This may be done by administering hGH in a time-released formulation, such as a microsphere formulation (Nutropin Depot®, Genentech, San Francisco, CA)), and how the monthly dose is calculated (“To calculate the monthly dose, individualized bioavailability data are determined, since the microsphere formulation has 10-20% less bioavailability than daily dose formulations”).

7. Applicant has amended the claim as suggested by the Examiner.

8. Applicant respectfully disagrees with the Examiner’s rejection. Claim 10 does recite “administering said dose producing said optimal response as a maintenance dose.”

9. Applicant respectfully disagrees that there is insufficient antecedent basis. Antecedent basis is found in claim 10.

Applicant thus believes the above amendments and explanations fully overcome the rejections under 35 U.S.C. § 112 ¶ 2, and request their withdrawal.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102

Claims 1, 4, 7-10 and 13 are rejected under 35 U.S.C. § 102(b) as anticipated by Drake. Applicant respectfully disagrees that Drake discloses each and every limitation of the claims. In further support, applicant has provided a Declaration addressing the differences between the claimed invention and Drake.

The Declaration, submitted as part of this Amendment, distinguishes Drake in that Drake discloses a “dose titration regimen based solely on restoration of serum IGF-1 to the upper part of the age-related reference range” (emphasis added).

As applicant states, Drake discloses a uniform titration regimen based on a defined target range of serum IGF-1. The claimed invention does not have a defined target; rather, it requires an individualized dose, and recite steps for determining this individualized dose.

Claims 1, 4-10, 13, 14 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Murray. Applicant respectfully disagrees that Murray discloses each and every limitation of the claims. In further support, applicant has provided a Declaration addressing the differences between the claimed invention and Murray.

Specifically, the Declaration points to Murray's admission that the ideal dosing regimen and determinants of the maintenance dose for hGH have yet to be elucidated. In contrast, the invention provides the ideal dosing regimen and determinants of the maintenance dose. Thus, applicant asserts that Murray does not anticipate the claimed invention.

Attached hereto is a marked-up version of the changes made by the current amendment. The attached page is captioned **"Version with markings to show changes made"**.

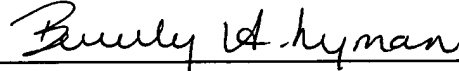
CONCLUSION

Applicant has submitted all fees believed to be necessary herewith. Should any additional fees or surcharges be deemed necessary, the Examiner has authorization to charge fees or credit any overpayment to Deposit Account No. 23-3000. Attached hereto is a marked-up version of the changes made by the current amendment.

The Examiner is invited to contact the undersigned attorney if there are any questions or issues.

Respectfully submitted,

WOOD, HERRON & EVANS L.L.P.

A handwritten signature in cursive script, reading "Beverly A. Lyman", written over a horizontal line.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 4 and 18 have been canceled.

Claims 7 and 13 have been amended as follows:

7. (AMENDED) The method of claim 1 wherein said response comprises increased insulin like growth factor1 levels.

13. (AMENDED) The method of claim 10 wherein said response is evaluated by evaluating a level of insulin like growth factor1.

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